

recognized in the United States Pharmacopoeia, an official compendium, but its quality and purity fell below the standard set forth therein since it was not sterile but was contaminated with living micro-organisms; and its difference in quality and purity from the official standard was not plainly stated on its label.

The article was alleged to be misbranded in that its label failed to bear an accurate statement of the quantity of contents in terms of numerical count.

On May 1, 1945, no claimant having appeared, judgment of condemnation was entered and it was ordered that the product be sold, on condition that the packages be stamped "Not sterilized and not to be used on open wounds or as a surgical dressing," and that the product was not to be resold by the purchaser.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS *

DRUGS FOR HUMAN USE**

- 1377. Misbranding of Ray-D Tablets. U. S. v. Nion Corporation. Plea of nolo contendere. Fine, \$250. (F. D. C. No. 9672. Sample No. 64965-E.)**

On December 1, 1943, the grand jurors for the Southern District of California returned an indictment against the Nion Corporation, Los Angeles, Calif., alleging shipment of a quantity of the above-named article from the State of California into the State of New York between the approximate dates of February 11 and 19, 1942.

Analysis disclosed that the article contained, per tablet, 10 International Units of vitamin B₁, 23 micrograms of riboflavin, and not more than 250 U. S. P. units of vitamin D.

The article was alleged to be misbranded in that certain statements in an accompanying circular were misleading since they represented and implied that the article would be efficacious in the cure, mitigation, treatment, or prevention of impairment of the digestive function, reduction of the motility of the bowel muscle, faulty elimination, malnutrition, and failure to gain weight resulting from lack of vitamin D and the members of the vitamin B complex; that the conditions referred to frequently result from lack of those vitamins; and that the reader might reasonably expect correction and relief from those conditions by use of the product. The article contained inconsequential amounts of vitamin D and the members of the vitamin B complex. The diseases and ailments named usually result from causes other than lack of vitamin D and the members of the vitamin B complex, and a product containing those vitamins would not ordinarily correct and relieve such conditions.

On October 17, 1944, a plea of nolo contendere having been entered on behalf of the defendant, the court imposed a fine of \$250.

- 1378. Misbranding of Macu Brand Papaya Concentrate. U. S. v. Macu Fruit Products. Motion to quash denied. Plea of guilty. Fine, \$200 and costs. (F. D. C. No. 10602. Sample No. 43991-F.)**

On February 9, 1944, the United States attorney for the Northern District of Illinois filed an information against Macu Food Products, a corporation, Chicago, Ill., alleging shipment of a quantity of Papaya Concentrate on or about April 17, 1943, from the State of Illinois into the State of Missouri. The article was labeled in part: "Macu Brand Papaya Concentrate."

The article was alleged to be misbranded in that certain statements in an accompanying circular were false and misleading. It was also alleged to be misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods, No. 7921, in which are set forth the results of analysis, and in which are indicated the nature of the false and misleading statements referred to above.

On June 12, 1944, the court entered an order overruling the defendant's motion to quash the information. Thereafter, a plea of guilty was entered on behalf of the defendant, and on November 6, 1944, the court imposed a fine of \$200 and costs.

- 1379. Misbranding of Colon-ease Herb Tea, Sapomin, Bulko, and Sootherklean. U. S. v. Louis L. Sherman, M. D. (The Layman's Academy of Health). Plea of nolo contendere. Fine, \$40. (F. D. C. No. 11434. Sample No. 42890-F.)**

On July 27, 1944, the United States attorney for the Northern District of California filed an information against Louis L. Sherman, M. D., trading as the Lay-

*See also Nos. 1351-1360, 1363, 1365-1367, 1369, 1373.

**See also No. 1397.

man's Academy of Health at Oakland, Calif., alleging shipment of a package containing the above-named products on or about October 5, 1943, from the State of California into the State of Washington.

Analysis of the Colon-ease Herb Tea showed that the article consisted essentially of plant material including buchu leaves, cassia bark, juniper berries, celery seed, licorice, and other roots, stems, and leaves. The article was alleged to be misbranded (1) in that the name "Colon-ease" was false and misleading since it suggested and implied that the article would ease the colon, whereas the article would not ease the colon; and (2) in that the statement "Colon-ease," on the jar label, and the statements in the accompanying circular entitled "Directions for Using Package 285," which represented and suggested that the article would ease the colon, keep mucus and scum moving along, aid digestion, relieve gas, aid in the assimilation of food, help stimulate the stomach and liver, relieve nervous tension, sooth the nervous system, help to keep the eliminating organs in a more healthy condition, and make life more worth while were false and misleading since the article would not accomplish the results claimed.

Analysis of the Sapomin showed that the article consisted essentially of small proportions of compounds of calcium, sodium, and aluminum sulfates; traces of compounds of magnesium and iron, chlorides, carbonates, and phosphates; and soap. The article was alleged to be misbranded in that it was not designated solely by a name recognized in an official compendium; and it was fabricated from two or more ingredients and its label failed to bear the common or usual name of each active ingredient since neither the statement, "Soap Minerals," nor the statement, "Contains: Oxides of Calcium, Magnesium, Silica, Aluminum, Iron, combined with Sulphates and Carbonates. A little powdered soap is added to help dissolve the minerals," borne on the jar label, constituted a statement of the active ingredients of the article by their common names.

Analysis of the Bulko showed that the product consisted essentially of a vegetable gum such as bassorin, a mucilaginous substance such as psyllium, calcium phosphate, dextrose, senna, and other plant material. The article was alleged to be misbranded (1) in that the name "Bulko" was misleading since it represented and implied that the article was solely a bulk-producing preparation, whereas it was not solely a bulk-producing preparation, but contained, in addition, irritant laxative drugs, mandrake and senna; and (2) in that the statement on the carton, "Bulko * * * May be used * * * with detoxication plan," was false and misleading since it represented and suggested that the article alone or in combination with the other articles in the detoxication package would be efficacious in detoxifying the system, whereas the article would not be efficacious for such purpose.

Analysis of the Sootherklean showed that the article consisted essentially of calcium gluconate and phosphate; magnesium sulfate; sodium citrate, bicarbonate, and phosphate; tartaric acid; and cornstarch. The article was alleged to be misbranded (1) in that the name "Sootherklean" was misleading since it represented and implied that the article would soothe and clean the alimentary canal, whereas the article would not be efficacious for such purpose; and (2) in that certain statements on the carton and in the afore-mentioned circular were false and misleading since they represented and suggested that the article would help sweeten and clean the stomach and duodenum, give nature a cleaner place for digestion, and clean the stomach and duodenum of mucus and phlegm, catarrh, or germs that had been swallowed from the teeth, tonsils, and sinus disease. The article would not be efficacious for such purposes.

The articles were alleged to be misbranded further in that the statements in the accompanying circular which represented and suggested that the articles alone or in combination with each other would be efficacious in assuring good health, digestion, assimilation, and the daily elimination of poisons; that they would help the various eliminating organs "Oxydize" and rid the system of poisons; and that they would assist in overcoming kinks and dropped conditions of the colon were false and misleading since the articles, either alone or in combination with each other, would not be efficacious for the purposes recommended.

On August 10, 1944, a plea of nolo contendere having been entered, the defendant was fined \$10 on each of 4 counts, a total fine of \$40.